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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,875	01/21/2002	Bernhard B. Sterling	OPTIS.039A	9479
20995	7590	07/01/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			PUNNOOSE, ROY M	
			ART UNIT	PAPER NUMBER
			2877	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,875

Applicant(s)

STERLING ET AL.

Examiner

Roy M. Punnoose

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A

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13,15-19,21-42,62-70 and 72-76 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13,15-19,21-42,62-70 and 72-76 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/2/02; 6/2/03</u> . | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

1. Applicant is advised that the Notice of Allowance mailed on November 18, 2003 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

2. Prosecution on the merits of this application is reopened on claims 1-13, 15-19, 21-42, 62-70 and 72-76 are considered unpatentable for the reasons indicated below:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5, 62 and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Neufeld (US 4,569,589).

Neufeld discloses a blood analyte detection system comprising an IR source 18, a detector 30, a housing 25 (see Figure 1, frame 25) for the source 18 and detector 30, a sample element/cuvette 28 (see Figure 1, densitometer cell 28) in the optical path including a sample cell wall 54 (see Figure 3, metal block 54) and a transmissive cell wall 84 (window 84), and a filtering system (filter wheel 12) transmitting radiation of about 4.2 microns (see col.4, lines 27-33, about 4 microns), a signal processor (see Figure 7), a sample extractor (see col.4, lines 45-47,

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catheter), wherein the sample element 28 comprises an opening 58 in fluid communication with the sample cell.

Neufeld also discloses that the IR bands typically have +/-0.5 micron bandwidth (see col.4, lines 48-53).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 16-19 and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neufeld (US 4,569,589).

In view of Neufeld's teachings of configuring a filter system to transmit in the 4 microns range, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate a filtering system to filter out or transmit wavelength in any other range for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

7. Claims 2-4, 6-13, 35-36 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neufeld (US 4,569,589) in view of Poto et al (US 5,795,543).

8. Claims 2, 6-13, 35-36 and 63-64 are rejected because:

A) Neufeld teaches all claim limitations as disclosed above except for a sample element comprising an analyte that is configured to be advanced into a portable housing of the system, wherein the sample element comprises a test strip for the purpose

of efficiently transferring the sample analyte into or out of said system for measuring the constituents of whole-blood.

B) Poto et al (Poto hereinafter) discloses a sample element 12 that is a test strip (see col.4, lines 29-41) comprising an analyte that is configured to be advanced manually into the housing (see Figure 1) of the system for the purpose of efficiently transferring the sample analyte into or out of said system for measuring the constituents of whole-blood.

C) In view of Poto's teachings, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate a sample element comprising an analyte, wherein the sample element comprises a test strip, that is configured to be advanced or automatically into the housing of the system, into Neufeld's system for the purpose of efficiently transferring the sample analyte into or out of said system for measuring the constituents of whole-blood.

Note: With regard to claims 8-13, in view of Poto's teachings, it would have been obvious to one of ordinary skills in the art at the time the invention was made to use the test strip only once, or, more than once, or, who uses it, or, the type of environment it is used, or, the type of sample analyte placed on the test strip.

9. Claims 3 and 4 are rejected because:

A) Neufeld teaches all claim limitations as disclosed above except for the explicit teaching of the orientation, either horizontal or vertical orientation, of a sample cell/element comprising an analyte that is configured to be advanced into the housing of the system for the purpose of efficiently transferring the sample analyte into or out of said system for measuring the content of the analyte.

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B) Poto et al (Poto hereinafter) discloses a sample element 12 comprising an analyte that is configured to be advanced in the horizontal orientation into the housing (see Figure 1) of the system for the purpose of efficiently transferring the sample analyte into or out of said system for measuring the content of the analyte.

C) In view of the teaching of Poto, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate any desired orientation, either horizontal or vertical orientation, of the sample cell/element comprising an analyte that is configured to be advanced into the housing of the system into Neufeld's system for the purpose of efficiently transferring the sample analyte into or out of said system for measuring the content of the analyte.

10. Claims 15, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neufeld (US 4,569,589) in view of Poto et al (US 5,795,543) and further in view of Fodgaard et al (US 5,817,007).

11. Claim 15 and 72 are rejected because:

A) Neufeld and Poto teach all claim limitations as disclosed above except for the use of a tunable filter configured to transmit spectral band of radiation at various wavelength ranges filtering system to filter out or transmit a desired wavelength range for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

B) Fodgaard et al (Fodgaard hereinafter) discloses the use of a tunable filter (see col.6, lines 27-39) configured to transmit spectral band of radiation at various wavelength ranges filtering system to filter out or transmit a desired wavelength range for

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the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

C) In view of Fodgaard's teaching, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate a tunable filter configured to transmit spectral band of radiation at various wavelength ranges filtering system to filter out or transmit a desired wavelength range for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

12. Claims 21-25 and 65-69 are rejected because:

A) Neufeld and Poto teach all claim limitations as disclosed above except for the explicit disclosure of an optical path length for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

B) Fodgaard et al (Fodgaard hereinafter) discloses optical path length of 0.5 mm to 2.0 mm (see abstract) for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

C) In view of Fodgaard's teaching, it would have been obvious to one of ordinary skills in the art at the time the invention was made to have an optical path of any desired length for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

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13. Claims 26-34 and 37-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neufeld (US 4,569,589) in view of Poto et al (US 5,795,543) and Fodgaard et al (US 5,817,007) and further in view of Clift (US 5,452,716).

14. Claims 29-34 are rejected because:

A) Neufeld, Poto and Fodgaard teach all claim limitations as disclosed above except for the explicit disclosure of cell wall optical characteristics for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

B) Clift discloses the use of a crystal cell wall 52 (see Figure 19) for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

C) In view of Clift's teaching, it would have been obvious to one of ordinary skills in the art at the time the invention was made to have cell wall made of any desired material having any desired optical characteristics for the purpose of efficiently detecting various contents of a sample analyte in a system for measuring the constituents of whole-blood.

15. Claims 26-28 and 37-42 are rejected because Clift discloses a blood detection system including a display (see col.10, lines 35-37) and a housing 60 (see Figure 19) having source 51 and detector 55, signal processor (computer 57), and a sample element having at least one optically transmissive portion (window 52). It would have been obvious to one of ordinary skills in the art to include a display, as disclosed by Clift, in the system disclosed by Neufeld for rapid assessment of blood chemistry. It is noted that the sample extractor disclosed by Neufeld and

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Clift is not integrated in the housing. However, the integration of structure is not generally considered to impart patentability. See also page 36 of the instant application.


With regard to claims 39-42, it is generally known in the art that computers have audible and visual displays and that various sections of a computer, such as display, input devices such as keyboard, mouse, etc. are modular and/or detachable, and the incorporation of such modular devices would have been obvious to one of ordinary skill in the art at the time of the invention.

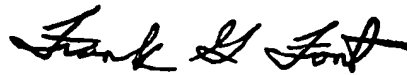
Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Roy M. Punnoose** whose telephone number is **571-272-2427**. The examiner can normally be reached on 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Frank G. Font** can be reached on **571-272-2415**. The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Roy M. Punnoose 
Patent Examiner
Art Unit 2877
June 21, 2004



Mr. Frank G. Font
Supervisory Patent Examiner